510(k) Summary

OCT 19 2010

Company Name:	WR Medical Electronics CO.
Device Name:	Heart Rate Variability Device
510(k) Sponsor, Contact:	WR Medical Electronics CO. 123 North 2nd Street Stillwater, MN 55082 Jack Blais, President Phone: (651) 430-1200 Fax: (651) 439-9733
Summary Date:	October 18, 2010
Common Name:	Heart Rate Variability Device
Classification Name:	Cardiac monitor, 21 CFR 870.2300, Product Code: DRT, Class II
Predicate Device(s):	K941252, ANX 3.0 K070795, SphygmoCor™ Cardiac Vascular Management System K882118, K023616, IVY ECG

1.0 Description of Device

The HRV Acquire (HRV) Device with TestWorks software can be used as a standalone cardiovagal device to support heart rate variability testing and expiratory pressure evaluation during valsalva breathing testing. The HRV device supports measurement of heart rate variability, respiratory effort from commercially available circumferential chest bellows, display of a valsalva breathing metronome breathing cue and display of non-invasive beat to beat blood pressure from an external device. An example of an external blood pressure device is the commercially available FMS Finometer, cleared to market by 510(k) K880572. Other commercially available, FDA cleared to market external beat to beat blood pressure devices with an analog blood pressure signal output may be applied.

The HRV device user interface is integrated into the existing WR Medical Electronics CO TestWorks software. The Test Works software was cleared to market with the Q-Sweat device, 510(K) K992874. The TestWorks software is modified to support an interface to the HRV device.

The HRV device may be mounted to a standard IV Pole.

The HRV device has two modes of operation:

1) Valsalva Mode supporting valsalva breathing cue to the subject under test,
2) Heart Rate Deep Breathing (HRDB) Mode.

In both modes, the HRV device acquires and the TestWorks software displays heart rate and blood pressure. The HRV device eliminates the need for a separate ECG acquisition device when these types of studies are performed. The HRV device acquires a Lead II ECG signal.

The HRV device and TestWorks software do not supply any alarms. All interpretation of acquired and displayed data is the responsibility of the physician/clinician supervising the test.

1.1 Variations and Accessories

There are no variations of HRV device.

2.0 Intended use of Device

The Heart Rate Variability (HRV) Acquire device is intended to record and indicate the following parameters during autonomic testing maneuvers:

- Expiratory pressure recording and display
- Respiratory effort
- Breathing cue metronome
- Heart rate via electrocardiography (ECG)
- Non-invasive beat-to-beat blood pressure from optional external device

The HRV Acquire does not make a diagnosis or indicate by itself any disease state exists. The HRV Acquire is not designed for vital signs monitoring or self monitoring of patients.

3.0 Technological Characteristics

The HRV Acquire device consolidates several components used in the autonomic lab for heart rate variability testing. The primary functions of the HRV Acquire are summarized as:

1. ECG capture of patient heart rate data,
2. Analog data acquisition,
3. Chest Expansion and Expiratory Pressure Capture,
4. Patient cueing metronome for breathing rate,
5. Expiratory pressure target and feedback.

The HRV Acquire deice provides ECG signal acquisition (3-lead), inputs for a chest expansion bellows and a valsalva expiratory pressure, and an analog input for an external continuous blood pressure device (optional). In addition, the HRV Acquire device has a large LED display consisting of six 5x7 dot matrix display elements used for patient cueing of a metronome pattern or feedback of valsalva pressure.

The HRV Acquire device includes firmware to provide R-wave detection trigger pulses for heart rate autonomic nervous system diagnostic procedures. The HRV Acquire device is replacing the IVY 101 Patient Monitor which was used for the same purpose of heart rate detection.

The HRV Acquire device will be used in medical research labs and clinics along with the TestWorks software package to support autonomic testing. There are no controls on the device, other than a power ON/OFF switch.

3.1 Comparison to Predicates

Feature	HRV AQUIRE Device with modified TestWorks Software Under Review	Predicate ANX 3.0 (K941252)	Predicate SphygmoCor™ Cardiac Vascular Management System (K070795)	Predicate IVY ECG Monitor (K882118, K023616)	Comments
Intended Use, Indications for Use	The Heart Rate Variability (HRV) Acquire device is intended to record and indicate the following parameters during autonomic testing maneuvers: - Expiratory pressure recording and display - Respiratory effort - Breathing cue metronome - Heart rate via electrocardiography (ECG) - Non-invasive beat-to-beat blood pressure from optional device The HRV Acquire is not designed for vital signs monitoring or self monitoring of patients.	Ansar's ANX 3.0 is an Autonomic Nervous System monitoring technology which measures both branches of the Autonomic Nervous System (the sympathetic and the parasympathetic) independently and simultaneously in real-time.	The CvMS Heart Rate Variability (HRV) option is intended for use in obtaining HRV measurements in response to controlled exercises.	The Ivy ECG and Heart Rate monitor is a precision ECG patient monitor intended to provide a precisely timed trigger pulse, synchronized with a patient's R-wave. It displays a single ECG waveform, large heart rate, alphanumeric characters for other data, alarm messages, menus and user information.	The HRV Device is applied to perform evaluations of the autonomic nervous system, like the predicate ANSAR and CvMS Devices. The user interface to the HRV Device is through the Test Works software, which is also the user interface to the WR Medical Q-Sweat device, reference 510(k) K K992874. The HRV Device contains ECG and Heart Rate functions to replace use of the IVY ECG device during autonomic nervous system evaluations.
Environment of Use	Hospital, Clinic, Physician Office	Hospital, Clinic, Physician Office	Hospital, Clinic, Physician Office	Hospital, Clinic, Physician Office	Same
Duration of use	Diagnostic testing expected to be less than one hour duration.	Diagnostic testing expected to be less than one hour duration.	Diagnostic testing expected to be less than one hour duration.	Diagnostic testing expected to be less than one hour duration.	Same
PC Based User Interface Software	Yes WR Medical TestWorks Software	Yes	Yes	Yes Test Works Software	Equivalent
Energy Type	AC Powered 120 VAC Nominal	AC Powered 120 VAC Nominal	AC Powered 120 VAC Nominal	AC Powered 85 to 264 VAC	Same
Size	10.25 x 6.57 x 1.26 (inches)	Unknown	12 x 10.3 x 5.3 (inches)	6.70 x 9.25 x 9.21 (inches)	Equivalent
Weight	2 pounds	Unknown	5.5 pounds	6.5 pounds	Equivalent

Feature	HRV AQUIRE Device with modified TestWorks Software Under Review	Predicate ANX 3.0 (K941252)	Predicate SphygmoCor™ Cardiac Vascular Management System (K070795)	Predicate IVY ECG Monitor (K882118, K023616)	Comments
ECG Specs	CMRR: 90 bB Lead Selection: Lead II Ground Isolation: 4 kV rms, 5.5 kV peak Input Impedance: 20 MOhm at 10 Hz Frequency Response: 0.2 to 100 Hz	Unknown specification	Lead Selection: Lead II Frequency Response: 0.5 to 30 Hz	CMRR: 90 bB Lead Selection: LI, LII, LIII Ground Isolation: 4 kV rms, 5.5 kV peak Input Impedance: 20 MOhm at 10 Hz Frequency Response: 0.5 to 25 Hz	Equivalent. The HRV Device ECG specifications are defined to support a diagnostic test.
R Wave Detection	Yes Range: 15 to 300 bpm Accuracy: ± 2% Resolution: 1 bpm Sensitivity: 300 µV peak Tall T Wave Rejection: Rejects T waves < R wave	Yes Unknown specification	Yes Unknown specification	Yes Range: 15 to 300 bpm Accuracy: ±1% Resolution: 1 bpm Sensitivity: 300 µV peak Tall T Wave Rejection: Rejects T waves < R wave	Equivalent The HRV Acquire is not an ECG monitor. The HRV Acquire is applied to determine changes in heart rate under defined test conditions.
Respiration Rate Metronome	Yes 2-20 seconds	Unknown	Yes	No	A display of respiration rate metronome is provided to pace the respiration rate of the patient under test.
Valsalva Target and Trigger Pressure Setting	Yes 2 to 50 mmHg	Yes Unknown range	Yes Breath against 40 mmHg	No	Equivalent
Alarms	No	No	No	Yes Heart Rate	Same The HRV Device is a diagnostic test device, not a monitoring device.
Safety Standards Compliance	EN/IEC 60601-1 EN/IEC 60601-1-2 AAMI/ANSI EC13	Unknown	EN/IEC 60601-1 EN/IEC 60601-1-2	EN/IEC 60601-1 EN/IEC 60601-1-2	Additional applicable FDA Recognized Consensus Standards are applied to evaluate the R-R heart rate detection. Compliance is documented in Section 9.0.

4.0 Data Summary

Testing of the Heart Rate Variability device was performed in compliance with the WR Medical Electronics CO. design control process. Testing included:

1. Software verification and validation,
2. System verification,
3. Confirmation of compliance with applicable requirements defined in AAMI EC13:2002/(R)2007 Cardiac monitors, Heart Rate Meters and Alarms, and
2. Safety standard compliance.

5.0 Conclusions

The safety and effectiveness of the Heart Rate Variability device was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Heart Rate Variability device is the same as the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

WR Medical Electronics Corporation
c/o Mr. Gary Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, WI 53589

OCT 19 2010

Re: K092809
Trade/Device Name: HRV Acquire
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (two)
Product Code: DRT
Dated: October 12, 2010
Received: October 13, 2010

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1/1

Indications for Use

510(k) Number (if known): K092809

K092809

Device Name: Heart Rate Variability Device

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092809